

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

## ELECTRO-MECHANICAL SURGICAL DEVICE

### CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of U.S. Patent Application Serial No.

5      09/836,781, filed on April 17, 2001, which is a continuation-in-part of U.S. Patent  
Application Serial No. 09/723,715, filed on November 28, 2000, which is a  
continuation-in-part of U.S. Patent Application Serial No. 09/324,451, filed on  
June 2, 1999, a continuation-in-part of U.S. Patent Application Serial No.  
09/324,452, filed on June 2, 1999, a continuation-in-part of U.S. Patent Application  
10     Serial No. 09/351,534, filed on July 12, 1999, a continuation-in-part of U.S. Patent  
Application Serial No. 09/510,923, filed on February 22, 2000, which is a  
continuation-in-part of U.S. Patent Application Serial No. 09/324,452, a continuation-  
in-part of U.S. Patent Application Serial No. 09/510,927, filed on February 22, 2000,  
which is a continuation-in-part of U.S. Patent Application Serial No. 09/324,452, and  
15     a continuation-in-part of U.S. Patent Application Serial No. 09/510,932, filed on  
February 22, 2000.

### FIELD OF THE INVENTION

The present invention relates to an electro-mechanical surgical device.

20

### BACKGROUND INFORMATION

The literature is replete with descriptions of surgical devices. For example, U.S. Patent No. 4,705,038 to Sjostrom et al. describes a surgical system for powered instruments. The system includes a handpiece containing a motor and  
25     including a recess adapted to receive one of a plurality of surgical devices. A pair of

reed switches is disposed within the recess, and each of the surgical devices includes one or two magnets adapted to actuate the reed switches in a particular combination when the device is assembled with the handpiece. The combination of reed switches activated by the magnets of the assembled handpiece and surgical

5 device identifies to the system the surgical device so assembled with the handpiece.

The number of possible surgical devices identifiable by this system is limited to the four possible combination of up to two magnets.

U.S. Patent No. 4,995,877 to Ams et al. describes a device with a rotationally-driven surgical instrument. The device includes a hand-held element containing a driving motor for driving a tool insert. The device further includes a control unit having a storage unit for storing operational data manually set by the user of the device. Such data may be transferred to a code carrier, which is insertable into a plug-in facility.

U.S. Patent No. 5,249,583 to Mallaby describes an electronic biopsy instrument with wiperless position sensors. A slotted disc and a cam are affixed to a drive shaft, which is driven by a motor. A pair of sensors is arranged so that each sensor is activated when the slot of the slotted disc is positioned over the sensor to thereby determine the position of a cannula and a stylet of the instrument. The sensors, slotted disc, cam, motor and rechargeable batteries for powering the

20 instrument are contained within a housing of the instrument.

U.S. Patent No. 5,383,880 to Hooven describes an endoscopic surgical system with sensing means. The instrument includes a motor disposed within a hand-held housing. A sensor is provided in the head of an instrument of the system for sensing the blood oxygen content of adjacent tissue.

5

Similarly, U.S. Patent No. 5,395,033 to Byrne et al. describes an endoscopic surgical instrument having a pair of jaws. A permanent magnet is disposed in a distal end of one of the jaws, and a magneto-resistive sensor is disposed in a distal end of the other one of the jaws. The magnet produces a magnetic field between the jaws, and the sensor measures the variations in the magnetic field so that the distance between the jaws may be determined.

U.S. Patent No. 5,467,911 to Tsuruta et al. describes a surgical device for stapling and fastening body tissues. The device includes an operation section and an insertion section, which is detachably attachable to the operation section.

10 U.S. Patent Nos. 5,518,163, 5,518,164 and 5,667,517, all to Hooven, describe an endoscopic surgical system, which includes a motor disposed in a handle portion. A sensing member, which is used to sense the blood oxygen content of adjacent tissue, is disposed in a head of the instrument. A contact is also provided in the head of the instrument. When a firing nut of the system has moved forward in the head to drive and form surgical staples disposed therein, the firing nut engages the contact, thereby reversing the motor to retract the firing nut.

20

U.S. Patent No. 5,653,374 to Young et al., U.S. Patent No. 5,779,130 to Alesi et al. and U.S. Patent No. 5,954,259 to Viola et al. describe a self-contained powered surgical apparatus, which includes a motor assembly and power source disposed within a hand-held instrument body.

25

These instruments and systems described above suffer numerous disadvantages. For example, in several of the above-described instruments and systems, a motor is disposed within a handle of the instrument. Due to size considerations, these motors generally provide limited torque. In certain of the instruments and systems described above, a battery is provided within the handle

for powering the motor. Such battery systems, however, provide limited electrical power to the motors, further limiting the torque output by the motors.

In addition, it is generally not possible to accurately ascertain the positions of the operative elements of the aforementioned instruments and systems.

5 A further disadvantage of the above-described instruments and systems is that such instruments and systems typically require manual manipulation and operation. When a motor is provided in the handle of such instruments, manual manipulation and operation is awkward and cumbersome to the operator.

10 It is therefore an object of the present invention to provide an electro-mechanical surgical device, in which a motor system is provided remote from the surgical instrument.

It is a further object of the present invention to provide an electro-mechanical surgical device, which is operable via a remote control unit.

15 It is another object of the present invention to provide an electro-mechanical surgical device, in which the relative position of the components thereof may be accurately determined.

20 It is still another object of the present invention to provide an electro-mechanical surgical device, which includes a plurality of operating programs or algorithms. Each operating program or algorithm corresponds to a respective surgical instrument or attachment attachable to the electro-mechanical surgical device.

## SUMMARY

The above and other beneficial objects and advantages of the present invention are most effectively attained by providing an electro-mechanical surgical

5

device as described herein. In one example embodiment, an electro-mechanical surgical device includes: a housing; an elongated shaft extending from the housing, a distal end of the elongated shaft being detachably coupleable to a surgical instrument; at least two axially rotatable drive shafts disposed within the elongated shaft, a distal end of each of the drive shafts being configured to couple with the surgical instrument; a steering cable arrangement being configured to steer the distal end of the elongated shaft; and a motor system disposed within the housing and configured to drive the drive shafts and the steering cable arrangement.

10  
15  
20  
25  
30  
35  
40  
45  
50  
55  
60  
65  
70  
75  
80  
85  
90  
95  
100

In another example embodiment, the electro-mechanical surgical device includes a control system and a remote control unit configured to communicate with the control system to control the motor system via the control system. The remote control unit may include a wired remote control unit and/or a wireless remote control unit.

15

In yet another example embodiment, the electro-mechanical surgical device includes a sensor configured to detect the rotation of the drive shaft. The control system is configured to determine a position of the elements of the surgical instrument based on the detected rotation of the drive shaft.

20

In still another example embodiment, the electro-mechanical surgical device includes a first memory unit configured to store a plurality of operating programs or algorithms, each corresponding to a respective type of surgical instrument. The control system is configured to detect the type of surgical instrument attached to the electro-mechanical surgical device and to select or read the operating program or algorithm corresponding to the attached surgical instrument.

25

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of an electro-mechanical surgical device according to the present invention;

Figure 2 is a side elevational view, partially in section, of a flexible shaft of the electro-mechanical surgical device illustrated in Figure 1;

5           Figure 3 is a cross-sectional view of the flexible shaft taken along the line 3 - 3 shown in Figure 2;

Figure 4 is a rear end view of a first coupling of the flexible shaft illustrated in Figure 2;

10           Figure 5 is a front end view of a second coupling of the flexible shaft illustrated in Figure 2;

Figure 6 is a schematic view illustrating a motor arrangement of the electro-mechanical surgical device illustrated in Figure 1;

15           Figure 7 is a schematic view of the electro-mechanical surgical device illustrated in Figure 1;

Figure 8 is a schematic view of an encoder of the flexible shaft illustrated in Figures 2 and 3;

20           ~~Subj 2~~       Figure 9a is a schematic cross-sectional side view of a first example embodiment of a circular surgical stapler attachment used in connection with the electro-mechanical surgical device illustrated in Figure 1;

Figure 9a is a schematic cross-sectional side view of a second example embodiment of a circular surgical stapler attachment used in connection with the electro-mechanical surgical device illustrated in Figure 1;

25           Figure 9c is an exploded view of an example embodiment of a gear arrangement of the second example embodiment of the circular surgical stapler attachment illustrated in Figure 9b;

Su 1/3

Figure 10 is a schematic view of a memory device of the first example embodiment of a circular surgical stapler attachment illustrated in Figure 9b;

Figure 11 is a schematic view of a wireless remote control unit of the electro-mechanical surgical device illustrated in Figure 1;

5           Figure 12 is a schematic view of a wired remote control unit of the electro-mechanical surgical device illustrated in Figure 1;

Figure 13 illustrates a flowchart of a first example embodiment of a main operating program for operating the electro-mechanical surgical device illustrated in Figures 1;

10           Figures 14a to 14d illustrate a flowchart of a first example embodiment of a fire routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c;

Figures 15a and 15b illustrate a flowchart of a clamp routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c;

15           Figure 16 illustrates a flowchart of an unclamp routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c;

Figures 17a to 17d illustrate a flowchart of a second example embodiment of a main operating program for operating the electro-mechanical surgical device illustrated in Figure 1;

20           Figures 18a and 18b illustrate a flowchart of a self-test operating program for the electro-mechanical surgical device illustrated in Figure 1;

Figures 19a to 19e illustrate a flowchart for a field test operating program for the electro-mechanical surgical device illustrated in Figure 1;

Figures 20a to 20c illustrate a flowchart for a main operating program for operating the circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c;

5 Figures 21a to 21d illustrate a flowchart of a second example embodiment of a fire routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c;

Figures 22a and 22b illustrate a flowchart of a second example embodiment of a clamp routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c; and

10 Figures 23a and 23b illustrate a flowchart of a second example embodiment of an unclamp routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c.

#### DETAILED DESCRIPTION

15 Those skilled in the art will gain an appreciation of the present invention from a reading of the following description when viewed in conjunction with the accompanying drawings of Figures 1 to 23b, inclusive. The individual reference characters designate the same or similar elements throughout the several views.

20 Referring to Figure 1, there is seen a perspective view of an electro-mechanical surgical device 10 according to an example embodiment of the present invention. Electro-mechanical surgical device 10 may include, for example, a remote power console 12, which includes a housing 14 having a front panel 15. Mounted on front panel 15 are a display device 16 and indicators 18a, 18b, which are more fully described hereinbelow. A flexible shaft 20 may extend from housing 25 14 and may be detachably secured thereto via a first coupling 22. The distal end 24

of flexible shaft 20 may include a second coupling 26 adapted to detachably secure a surgical instrument or attachment to the distal end 24 of flexible shaft 20. The surgical instrument or attachment may be, for example, a surgical stapler, a surgical cutter, a surgical stapler-cutter, a linear surgical stapler, a linear surgical stapler-cutter, a circular surgical stapler, a circular surgical stapler-cutter, a surgical clip applier, a surgical clip ligator, a surgical clamping device, a vessel expanding device, a lumen expanding device, a scalpel, a fluid delivery device or any other type of surgical instrument. Such surgical instruments are described, for example, in U.S. Patent Application Serial No. 09/324,451, entitled "A Stapling Device for Use with an Electromechanical Driver Device for Use with Anastomosing, Stapling, and Resecting Instruments," U.S. Patent Application Serial No. 09/324,452, entitled "Electromechanical Driver Device for Use with Anastomosing, Stapling, and Resecting Instruments," U.S. Patent Application Serial No. 09/351, 534, entitled "Automated Surgical Stapling System," U.S. Patent Application Serial No. 09/510,926, entitled "A Vessel and Lumen Expander Attachment for Use with an Electromechanical Driver Device," U.S. Patent Application Serial No. 09/510,927, entitled "Electromechanical Driver and Remote Surgical Instruments Attachment Having Computer Assisted Control Capabilities," U.S. Patent Application Serial No. 09/510,931, entitled "A Tissue Stapling Attachment for Use with an Electromechanical Driver Device," U.S. Patent Application Serial No. 09/510,932, entitled "A Fluid Delivery Mechanism for Use with Anastomosing, Stapling, and Resecting Instruments," and U.S. Patent Application Serial No. 09/510,933, entitled "A Fluid Delivery Device for Use with Anastomosing, Stapling, and Resecting Instruments," each of which is expressly incorporated herein in its entirety by reference thereto.

5

10

15

20

25

Referring to Figure 2, there is seen a side view, partially in section, of flexible

shaft 20. According to one embodiment, flexible shaft 20 includes a tubular sheath

28, which may include a coating or other sealing arrangement to provide a fluid-tight

seal between the interior channel 40 thereof and the environment. Sheath 28 may

be formed of a tissue-compatible, sterilizable elastomeric material. The sheath 28

may also be formed of a material that is autoclavable. Disposed within the interior

channel 40 of flexible shaft 20, and extending along the entire length thereof, may

be a first rotatable drive shaft 30, a second rotatable drive shaft 32, a first steering

cable 34, a second steering cable 35, a third steering cable 36, a fourth steering

cable 37 and a data transfer cable 38. Figure 3 is a cross-sectional view of flexible

shaft 20 taken along the line 3 - 3 shown in Figure 2 and further illustrates the

several cables 30, 32, 34, 35, 36, 37, 38. Each distal end of the steering cables 34,

35, 36, 37 is affixed to the distal end 24 of the flexible shaft 20. Each of the several

cables 30, 32, 34, 35, 36, 37, 38 may be contained within a respective sheath.

The first rotatable drive shaft 30 and the second rotatable drive shaft 32 may

be configured, for example, as highly flexible drive shafts, such as, for example,

braided or helical drive cables. It should be understood that such highly flexible

drive cables have limited torque transmission characteristics and capabilities. It

should also be understood that surgical instruments, such as the circular surgical

stapler attachment 250 illustrated in Figure 9a and the circular surgical stapler

attachments 2250 illustrated in Figures 9b and 9c and described below, or other

attachments detachably attachable to the flexible shaft 20 may require a higher

torque input than the torque transmittable by the drive shafts 30, 32. The drive

shafts 30, 32 may thus be configured to transmit low torque but high speed, the high

speed/low torque being converted to low speed/high torque by gearing

10 15

arrangements disposed, for example, at the distal end and/or the proximal end of the drive flexible shaft 20, in the surgical instrument or attachment and/or in the remote power console 12. It should be appreciated that such gearing arrangement(s) may be provided at any suitable location along the power train between the motors

Referring now to Figure 4, there is seen a rear end view of first coupling 22.

First coupling 22 includes a first connector 44, a second connector 48, a third connector 52 and a fourth connector 56, each rotatably secured to first coupling 22.

15 Each of the connectors 44, 48, 52, 56 includes a respective recess 46, 50, 54, 58

As shown in Figure 4, each recess 46, 50, 54, 58 may be hexagonally shaped. It

should be appreciated, however, that the recesses 46, 50, 54, 58 may have any shape and configuration to non-rotatably couple and rigidly attach the connectors

20 the housing 12, as more fully described below. It should be appreciated that complementary projections may be provided on respective drive shafts of the motor arrangement to thereby drive the drive elements of the flexible shaft 20 as described below. It should also be appreciated that the recesses may be provided on the drive shafts and complementary projections may be provided on the connectors 44, 48, 52, 56. Any other coupling arrangement configured to non-rotatably and releasably

25

couple the connectors 44, 48, 52, 56 and the drive shafts of the motor arrangement may be provided.

One of the connectors 44, 48, 52, 56 is non-rotatably secured to the first drive shaft 30, and another one of the connectors 44, 48, 52, 56 is non-rotatably secured to the second drive shaft 32. The remaining two of the connectors 44, 48, 52, 56 engage with transmission elements configured to apply tensile forces on the steering cables 34, 35, 36, 37 to thereby steer the distal end 24 of the flexible shaft 20. The data transfer cable 38 is electrically and logically connected with data connector 60. Data connector 60 includes, for example, electrical contacts 62, corresponding to and equal in number to the number of individual wires contained in the data cable 38. First coupling 22 includes a key structure 42 to properly orient the first coupling 22 to a mating and complementary coupling arrangement disposed on the housing 12. Such key structure 42 may be provided on either one, or both, of the first coupling 22 and the mating and complementary coupling arrangement disposed on the housing 12. First coupling 22 may include a quick-connect type connector, which may use, for example, a simple pushing motion to engage the first coupling 22 to the housing 12. Seals may be provided in conjunction with any of the several connectors 44, 48, 52, 56, 60 to provide a fluid-tight seal between the interior of first coupling 22 and the environment.

Referring now to Figure 5, there is seen a front end view of the second coupling 26 of flexible shaft 20. Second coupling 26 includes a first connector 66 and a second connector 68, each being rotatably secured to the second coupling 26 and each being non-rotatably secured to a distal end of a respective one of the first and second drive shafts 30, 32. A quick-connect type fitting 64 is provided on the second coupling 26 for detachably securing the surgical instrument or attachment

SEARCHED  
INDEXED  
SERIALIZED  
FILED

thereto. The quick-connect type fitting 64 may be, for example, a rotary quick-connect type fitting, a bayonet type fitting, etc. A key structure 74 is provided on the second coupling 26 for properly aligning the surgical instrument or attachment to the second coupling 26. The key structure or other arrangement for properly aligning  
5 the surgical instrument or attachment to the flexible shaft 20 may be provided on either one, or both, of the second coupling 26 and the surgical instrument or attachment. In addition, the quick-connect type fitting may be provided on the surgical instrument or attachment. A data connector 70, having electrical contacts 72, is also provided in the second coupling 26. Like the data connector 60 of first  
10 coupling 22, the data connector 70 of second coupling 26 includes contacts 72 electrically and logically connected to the respective wires of data transfer cable 38 and contacts 62 of data connector 60. Seals may be provided in conjunction with the connectors 66, 68, 70 to provide a fluid-tight seal between the interior of second coupling 26 and the environment.

15 Disposed within housing 14 of the remote power console 12 are electro-mechanical driver elements configured to drive the drive shafts 30, 32 and the steering cables 34, 35, 36, 37 to thereby operate the electro-mechanical surgical device 10 and the surgical instrument or attachment attached to the second coupling  
20 26. In the example embodiment illustrated schematically in Figure 6, five electric motors 76, 80, 84, 90, 96, each operating via a power source, may be disposed in the remote power console 12. It should be appreciated, however, that any appropriate number of motors may be provided, and the motors may operate via battery power, line current, a DC power supply, an electronically controlled DC power supply, etc. It should also be appreciated that the motors may be connected

to a DC power supply, which is in turn connected to line current and which supplies the operating current to the motors.

Figure 6 illustrates schematically one possible arrangement of motors. An output shaft 78 of a first motor 76 engages with the first connector 44 of the first coupling 22 when the first coupling 22, and, therefore, flexible shaft 20, is engaged with the housing 14 to thereby drive the first drive shaft 30 and first connector 66 of second coupling 26. Similarly, an output shaft 82 of a second motor 80 engages the second connector 48 of first coupling 22 when first coupling 22, and, therefore, flexible shaft 20 is engaged with the housing 14 to thereby drive the second drive shaft 32 and second connector 68 of second coupling 26. An output shaft 86 of a third motor 84 engages the third connector 52 of the first coupling 22 when the first coupling 22, and, therefore, flexible shaft 20, is engaged with the housing 14 to thereby drive the first and second steering cables 34, 35 via a first pulley arrangement 88. An output shaft 92 of a fourth motor 90 engages the fourth connector 56 of the first coupling 22 when the first coupling 22, and, therefore, flexible shaft 20, is engaged with the housing 14 to thereby drive the third and fourth steering cables 36, 37 via a second pulley arrangement 94. The third and fourth motors 84, 90 may be secured on a carriage 100, which is selectively movable via an output shaft 98 of a fifth motor 96 between a first position and a second position to selectively engage and disengage the third and fourth motors 84, 90 with the respective pulley arrangement 88, 94 to thereby permit the flexible shaft 20 to become taut and steerable or limp as necessary. It should be appreciated that other mechanical, electrical or electro-mechanical mechanisms may be used to selectively engage and disengage the steering mechanism. The motors may be arranged and configured as described, for example, in U.S. Patent Application Serial No.

09/510,923, entitled "A Carriage Assembly for Controlling a Steering Wire Mechanism Within a Flexible Shaft," which is expressly incorporated herein in its entirety by reference thereto.

It should be appreciated, that any one or more of the motors 76, 80, 84, 90, 5 96 may be high-speed/low-torque motors or low-speed/high-torque motors. As indicated above, the first rotatable drive shaft 30 and the second rotatable drive shaft 32 may be configured to transmit high speed and low torque. Thus, the first motor 76 and the second motor 80 may be configured as high-speed/low-torque motors. Alternatively, the first motor 76 and the second motor 80 may be configured 10 as low-speed/high-torque motors with a torque-reducing/speed-increasing gear arrangement disposed between the first motor 76 and the second motor 80 and a respective one of the first rotatable drive shaft 30 and the second rotatable drive shaft 32. Such torque-reducing/speed-increasing gear arrangement may include, for example, a spur gear arrangement, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, an epicyclic gear arrangement, etc. It 15 should be appreciated that any such gear arrangement may be disposed within the remote power console 12 or in the proximal end of the flexible shaft 20, such as, for example, in the first coupling 22. It should be appreciated that the gear arrangement(s) are provided at the distal and/or proximal ends of the first rotatable 20 drive shaft 30 and/or the second rotatable drive shaft 32 to prevent windup and breakage thereof.

Referring now to Figure 7, there is seen a schematic view of the electro-mechanical surgical device 10. A controller 122 is provided in the housing 14 of remote power console 12 and is configured to control all functions and operations of 25 the electro-mechanical surgical device 10 and any surgical instrument or attachment

0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

attached to the flexible shaft 20. A memory unit 130 is provided and may include memory devices, such as, a ROM component 132 and/or a RAM component 134. ROM component 132 is in electrical and logical communication with controller 122 via line 136, and RAM component 134 is in electrical and logical communication with controller 122 via line 138. RAM component 134 may include any type of random-access memory, such as, for example, a magnetic memory device, an optical memory device, a magneto-optical memory device, an electronic memory device, etc. Similarly, ROM component 132 may include any type of read-only memory, such as, for example, a removable memory device, such as a PC-Card or PCMCIA-type device. It should be appreciated that ROM component 132 and RAM component 134 may be embodied as a single unit or may be separate units and that ROM component 132 and/or RAM component 134 may be provided in the form of a PC-Card or PCMCIA-type device. Controller 122 is further connected to front panel 15 of housing 14 and, more particularly, to display device 16 via line 154 and indicators 18a, 18b via respective lines 156, 158. Lines 116, 118, 124, 126, 128 electrically and logically connect controller 122 to first, second, third, fourth and fifth motors 76, 80, 84, 90, 96, respectively. A wired remote control unit ("RCU") 150 is electrically and logically connected to controller 122 via line 152. A wireless RCU 148 is also provided and communicates via a wireless link 160 with a receiving/sending unit 146 connected via line 144 to a transceiver 140. The transceiver 140 is electrically and logically connected to controller 122 via line 142. Wireless link 160 may be, for example, an optical link, such as an infrared link, a radio link or any other form of wireless communication link.

A switch device 186, which may be, for example, an array of DIP switches,

25 may be connected to controller 122 via line 188. Switch device 186 may be used,

for example, to select one of a plurality of languages used in displaying messages and prompts on the display device 16. The messages and prompts may relate to, for example, the operation and/or the status of the electro-mechanical surgical device 10 and/or to any surgical instrument or attachment attached thereto,

5 According to the example embodiment of the present invention, a first encoder 106 is provided within the second coupling 26 and is configured to output a signal in response to and in accordance with the rotation of the first drive shaft 30. A second encoder 108 is also provided within the second coupling 26 and is configured to output a signal in response to and in accordance with the rotation of  
10 the second drive shaft 32. The signal output by each of the encoders 106, 108 may represent the rotational position of the respective drive shaft 30, 32 as well as the rotational direction thereof. Such encoders 106, 108 may be, for example, Hall-effect devices, optical devices, etc. Although the encoders 106, 108 are described as being disposed within the second coupling 26, it should be appreciated that the  
15 encoders 106, 108 may be provided at any location between the motor system and the surgical instrument or attachment. It should be appreciated that providing the encoders 106, 108 within the second coupling 26 or at the distal end of the flexible shaft 20 provides for an accurate determination of the drive shaft rotation. If the encoders 106, 108 are disposed at the proximal end of the flexible shaft 20, windup  
20 of the first and second rotatable drive shafts 30, 32 may result in measurement error.

Figure 8 is a schematic view of an encoder 106, 108, which includes a Hall-effect device. Mounted non-rotatably on drive shaft 30, 32 is a magnet 240 having a north pole 242 and a south pole 244. The encoder 106, 108 further includes a first  
25 sensor 246 and second sensor 248, which are disposed approximately 90° apart

10 15

relative to the longitudinal, or rotational, axis of drive shaft 30, 32. The output of the sensors 246, 248 is persistent and changes its state as a function of a change of polarity of the magnetic field in the detection range of the sensor. Thus, based on the output signal from the encoders 106, 108, the angular position of the drive shaft 30, 32 may be determined within one-quarter revolution and the direction of rotation of the drive shaft 30, 32 may be determined. The output of each encoder 106, 108 is transmitted via a respective line 110, 112 of data transfer cable 38 to controller 122. The controller 122, by tracking the angular position and rotational direction of the drive shafts 30, 32 based on the output signal from the encoders 106, 108, can thereby determine the position and/or state of the components of the surgical instrument or attachment connected to the electro-mechanical surgical device 10. That is, by counting the revolutions of the drive shaft 30, 32, the controller 122 can determine the position and/or state of the components of the surgical instrument or attachment connected to the electro-mechanical surgical device 10.

For example, in a circular surgical stapler attachment 250, such as that shown schematically in cross-section in Figure 9a, the circular surgical stapler attachment 250 includes a coupling 260 adapted by size and configuration to cooperate with the second coupling 26 of flexible shaft 20 to detachably attach the circular surgical stapler attachment 250 thereto. Circular surgical stapler attachment 250 includes an anvil portion 254 having an anvil 256 mounted on the distal end of an anvil stem 258. The anvil stem 258 is extended and retracted by the operation of an anvil drive shaft 262, which is rotatably secured within the body portion 252 of the circular surgical stapler attachment 250. A proximal end of the anvil drive shaft 262 includes a first connector 268 adapted by size and configuration to couple with the first connector 66 of second coupling 26. Circular surgical stapler attachment 250

0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
D  
O  
C  
H  
A  
R  
T

further includes a staple driver/cutter 264 driven by the rotation of a staple driver/cutter drive shaft 266. The proximal end of the staple driver/cutter drive shaft 266 includes a second connector 270, which is adapted by size and configuration to couple with the second connector 68 of second coupling 26. Thus, in the example 5 circular surgical stapler attachment 250 shown in Figure 9a, the extension and retraction of the anvil 256 is effected by the operation of the first motor 76, and the extension and retraction of the staple driver/cutter 264 is effected by the operation of the second motor 80. The pitch of the anvil drive shaft 262 and the pitch of the stapler driver/cutter drive shaft 266 are predetermined and known quantities. That 10 is, the advancement distance of the anvil 256 and the staple driver/cutter 264 are functions of, and ascertainable on the basis of, the rotation of the respective drive shaft 30, 32. By ascertaining an absolute position of the anvil 256 and the staple driver/cutter 264 at a point in time, the relative displacement of the anvil 256 and staple driver/cutter 264, based on the output signal from the encoders 106, 108 and 15 the known pitches of the anvil drive shaft 262 and staple driver/cutter drive shaft 266, may be used to ascertain the absolute position of the anvil 256 and staple driver/cutter 264 at all times thereafter. The absolute position of the anvil 256 and staple driver/cutter 264 may be fixed and ascertained at the time that the circular surgical stapler attachment 250 is first coupled to the flexible shaft 20. Alternatively, 20 the position of the anvil 256 and the staple driver/cutter 264 relative to, for example, the body portion 252 may be determined based on the output signal from the encoders 106, 108.

Circular surgical stapler attachment 250 further includes a data connector 272 adapted by size and configuration to electrically and logically connect to connector 25 70 of second coupling 26. In the example embodiment, data connector 272 includes

contacts (not shown) equal in number to the number of leads 72 of connector 70.

Contained within the circular surgical stapler attachment 250 is a memory unit 174 electrically and logically connected with the data connector 272. Memory unit 174 may be in the form of, for example, an EEPROM, EPROM, etc. and may be contained, for example, within the body portion 252 of circular surgical stapler attachment 250.

5 Figure 9b is a schematic cross-sectional view of a second example

embodiment of a circular surgical stapler attachment 2250. The circular surgical stapler attachment 2250 includes a coupling 2260 adapted by size and configuration to cooperate with the second coupling 26 of flexible shaft 20 to detachably attach the circular surgical stapler attachment 2250 thereto. Circular surgical stapler attachment 2250 includes an anvil portion 2254 having an anvil 2256 mounted on the distal end of an anvil stem 2258. The anvil stem 2258 may be detachably secured to a trocar 2274. The anvil stem 2258 is extended and retracted by the operation of an anvil drive shaft 2262, which is rotatably secured within the body portion 2252 of the circular surgical stapler attachment 2250. The anvil drive shaft 2262 may be externally threaded, and the trocar 2274 may be internally threaded at the proximal end 2276 thereof so that rotation of the anvil drive shaft 2262 causes the extension and retraction of the anvil stem 2258. A proximal end of the anvil 20 drive shaft 2262 includes a first connector 2268 adapted by size and configuration to couple with the first connector 66 of second coupling 26. Circular surgical stapler attachment 2250 further includes a staple driver/cutter 2264, which is driven by the rotation of a staple driver/cutter drive shaft 2266. The proximal end of the staple driver/cutter drive shaft 2266 includes a second connector 2270, which is adapted 25 by size and configuration to couple with the second connector 68 of the second

coupling 26. A gearing arrangement 2278 is disposed between the staple driver/cutter drive shaft 2266 and the staple driver/cutter 2264. The gearing arrangement 2278 may include, for example, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, an epicyclic gear arrangement, etc., which is configured to convert the high-speed/low-torque transmitted by the second rotating drive shaft 32 to low-speed/high-torque for ejecting and forming the staples, as more fully described herein. Figure 9c is an exploded view of the gearing arrangement 2278, which includes a planetary gear arrangement, namely four sets of planetary gears 2280a, 2280b, 2280c, 2280d. The operation of the second example embodiment of the circular surgical stapler attachment 2250 is similar to the operation of the first example embodiment of the circular surgical stapler attachment 250 as more fully set forth above.

Figure 10 schematically illustrates the memory unit 174. As seen in Figure 10, data connector 272 includes contacts 276, each electrically and logically connected to memory unit 174 via a respective line 278. Memory unit 174 is configured to store, for example, a serial number data 180, an attachment type identifier (ID) data 182 and a usage data 184. Memory unit 174 may additionally store other data. Both the serial number data 180 and the ID data 182 may be configured as read-only data. In the example embodiment, serial number data 180 is data uniquely identifying the particular surgical instrument or attachment, whereas the ID data 182 is data identifying the type of the attachment, such as, for example, a circular surgical stapler attachment, a linear surgical stapler attachment, etc. The usage data 184 represents usage of the particular attachment, such as, for example, the number of times the anvil 256 of the circular surgical stapler attachment 250 has

been advanced or the number of times that the staple driver/cutter 264 of the circular surgical stapler attachment 250 has been advanced or fired.

It should be appreciated that each type of surgical instrument or attachment attachable to the distal end 24 of the flexible shaft 20 may be designed and configured to be used a single time or multiple times. The surgical instrument or attachment may also be designed and configured to be used a predetermined number of times. Accordingly, the usage data 184 may be used to determine whether the surgical instrument or attachment has been used and whether the number of uses has exceeded the maximum number of permitted uses. As more fully described below, an attempt to use a surgical instrument or attachment after the maximum number of permitted uses has been reached will generate an ERROR condition.

It should be appreciated that the circular surgical stapler attachment 250 illustrated in Figure 9a is intended to be merely an example of a surgical attachment used in conjunction with the electro-mechanical surgical device 10. It should be further appreciated that any other type of surgical instrument or attachment, such as those enumerated hereinabove, may be used in conjunction with the electro-mechanical surgical device 10. Regardless of the particular type of surgical instrument or attachment, in the example embodiment of the present invention, the surgical instrument or attachment includes the coupling elements 268, 270, 272, as necessary for proper operation of the surgical instrument or attachment, as well as the memory unit 174. Although the drive shafts and motors are described herein as effecting particular functions of the circular surgical stapler attachment 250, it should be appreciated that the drive shafts and motors may effect the same or other functions of other types of surgical instruments or attachments.

0  
10  
20  
30  
40  
50  
60  
70  
80  
90  
100

Referring again to Figure 7, in accordance with the example embodiment of the present invention, the controller 122 is configured to read the ID data 182 from the memory unit 174 of the surgical instrument or attachment when the surgical instrument or attachment is initially connected to the flexible shaft 20. The memory unit 174 is electrically and logically connected to the controller 122 via line 120 of data transfer cable 38. Based on the read ID data 182, the controller 122 is configured to read or select from the memory unit 130, an operating program or algorithm corresponding to the type of surgical instrument or attachment connected to the flexible shaft 20. The memory unit 130 is configured to store the operating programs or algorithms for each available type of surgical instrument or attachment, the controller 122 selecting and/or reading the operating program or algorithm from the memory unit 130 in accordance with the ID data 182 read from the memory unit 174 of an attached surgical instrument or attachment. As indicated above, the memory unit 130 may include a removable ROM component 132 and/or RAM component 134. Thus, the operating programs or algorithms stored in the memory unit 130 may be updated, added, deleted, improved or otherwise revised as necessary. The operating programs or algorithms stored in the memory unit 130 may be customizable based on, for example, specialized needs of the user. A data entry device, such as, for example, a keyboard, a mouse, a pointing device, a touch screen, etc., may be connected to the memory unit 130 via, for example, a data connector port, to facilitate the customization of the operating programs or algorithms. Alternatively or additionally, the operating programs or algorithms may be customized and preprogrammed into the memory unit 130 remotely from the electro-mechanical surgical device 10. It should be appreciated that the serial number data 180 and/or usage data 184 may also be used to determine which of a

plurality of operating programs or algorithms is read or selected from the memory unit 130. It should be appreciated that the operating program or algorithm may alternatively be stored in the memory unit 174 of the surgical instrument or attachment and transferred to the controller 122 via the data transfer cable 38.

- 5 Once the appropriate operating program or algorithm is read or selected by, or transmitted to, the controller 122, the controller 122 causes the operating program or algorithm to be executed in accordance with operations performed by the user via the wired RCU 150 and/or the wireless RCU 148. As indicated hereinabove, the controller 122 is electrically and logically connected with the first, second, third,  
10 fourth and fifth motors 76, 80, 84, 90, 96 via respective lines 116, 118, 124, 126, 128 and controls such motors 76, 80, 84, 90, 96 in accordance with the read, selected or transmitted operating program or algorithm via the respective lines 116, 118, 124, 126, 128.

Referring now to Figure 11, there is seen a schematic view of wireless RCU 148. Wireless 148 includes a steering controller 300 having a plurality of switches 302, 304, 306, 308 arranged under a four-way rocker 310. The operation of switches 302, 304, via rocker 310, controls the operation of first and second steering cables 34, 35 via third motor 84. Similarly, the operation of switches 306, 308, via rocker 310, controls the operation of third and fourth steering cables 36, 37 via fourth motor 92. It should be appreciated that rocker 310 and switches 302, 304, 306, 308 are arranged so that the operation of switches 302, 304 steers the flexible shaft 20 in the north-south direction and that the operation of switches 306, 308 steers the flexible shaft 20 in the east-west direction. Reference herein to north, south, east and west is made to a relative coordinate system. Alternatively, a digital joystick, analog joystick, etc. may be provided in place of rocker 310 and switches  
20  
25

302, 304, 306, 308. Potentiometers or any other type of actuator may also be used in place of switches 302, 304, 306, 308.

Wireless RCU 148 further includes a steering engage/disengage switch 312, the operation of which controls the operation of fifth motor 96 to selectively engage 5 and disengage the steering mechanism. Wireless RCU 148 also includes a two-way rocker 314 having first and second switches 316, 318 operable thereby. The

operation of these switches 316, 318 controls certain functions of the electro-mechanical surgical device 10 and any surgical instrument or attachment attached to the flexible shaft 20 in accordance with the operating program or algorithm

10 corresponding to the attached surgical instrument or attachment, if any. For example, where the surgical instrument is a circular surgical stapler attachment 250, such as that shown in Figure 9a and described hereinabove, operation of the two-way rocker 314 may control the advancement and retraction of the anvil 256.

Wireless RCU 148 is provided with yet another switch 320, the operation of which 15 may further control the operation of the electro-mechanical surgical device 10 and any surgical instrument or attachment attached to the flexible shaft 20 in accordance with the operating program or algorithm corresponding to the attached surgical instrument or attachment, if any. For example, when the circular surgical stapler attachment 250 is attached to the flexible shaft 20, operation of the switch 320 initiates the advancement, or firing sequence, of the staple driver/cutter 264.

Wireless RCU 148 includes a controller 322, which is electrically and logically connected with the switches 302, 304, 306, 308 via line 324, with the switches 316, 318 via line 326, with switch 312 via line 328 and with switch 320 via line 330.

Wireless RCU 148 may include indicators 18a', 18b', corresponding to the indicators 25 18a, 18b of front panel 15, and a display device 16', corresponding to the display

DRAFT DRAFT DRAFT DRAFT DRAFT

device 16 of the front panel 15. If provided, the indicators 18a', 18b' are electrically and logically connected to controller 322 via respective lines 332, 334, and the display device 16' is electrically and logically connected to controller 322 via line 336. Controller 322 is electrically and logically connected to a transceiver 338 via line 340, and transceiver 338 is electrically and logically connected to a receiver/transmitter 342 via line 344. A power supply, not shown, for example, a battery, may be provided in wireless RCU 148 to power the same. Thus, the wireless RCU 148 may be used to control the operation of the electro-mechanical surgical device 10 and any surgical instrument or attachment attached to the flexible shaft 20 via wireless link 160.

Wireless RCU 148 may include a switch 346 connected to controller 322 via line 348. Operation of switch 346 transmits a data signal to the transmitter/receiver 146 via wireless link 160. The data signal includes identification data uniquely identifying the wireless RCU 148. This identification data is used by the controller 122 to prevent unauthorized operation of the electro-mechanical surgical device 10 and to prevent interference with the operation of the electro-mechanical surgical device 10 by another wireless RCU. Each subsequent communication between the wireless RCU 148 and the electro-mechanical device surgical 10 may include the identification data. Thus, the controller 122 can discriminate between wireless RCUs and thereby allow only a single, identifiable wireless RCU 148 to control the operation of the electro-mechanical surgical device 10 and any surgical instrument or attachment attached to the flexible shaft 20.

Based on the positions of the components of the surgical instrument or attachment attached to the flexible shaft 20, as determined in accordance with the output signals from the encoders 106, 108, the controller 122 may selectively enable

098602762000

or disable the functions of the electro-mechanical surgical device 10 as defined by the operating program or algorithm corresponding to the attached surgical instrument or attachment. For example, where the surgical instrument or attachment is the circular surgical stapler attachment 250 illustrated in Figure 9a, the firing function controlled by the operation of the switch 320 is disabled unless the space or gap between the anvil 256 and the body portion 252 is determined to be within an acceptable range. The space or gap between the anvil 256 and the body portion 252 is determined based on the output signal from the encoders 106, 108, as more fully described hereinabove. It should be appreciated that the switch 320 itself remains operable but that the controller 122 does not effect the corresponding function unless the space or gap is determined to be within the acceptable range.

Referring now to Figure 12, there is seen a schematic view of a wired RCU 150. In the example embodiment, wired RCU 150 includes substantially the same control elements as the wireless RCU 148 and further description of such elements is omitted. Like elements are noted in Figure 12 with an accompanying prime. It should be appreciated that the functions of the electro-mechanical surgical device 10 and any surgical instrument or attachment attached to the flexible shaft 20 may be controlled by the wired RCU 150 and/or by the wireless RCU 148. In the event of a battery failure, for example, in the wireless RCU 148, the wired RCU 150 may be used to control the functions of the electro-mechanical surgical device 10 and any surgical instrument or attachment attached to the flexible shaft 20.

As described hereinabove, the front panel 15 of housing 14 includes display device 16 and indicators 18a, 18b. The display device 16 may include an alpha-numeric display device, such as an LCD display device. Display device 16 may also include an audio output device, such as a speaker, a buzzer, etc. The display

DRAFT - DRAFT - DRAFT - DRAFT - DRAFT

device 16 is operated and controlled by controller 122 in accordance with the operating program or algorithm corresponding to a surgical instrument or attachment, if any, attached to the flexible shaft 20. If no surgical instrument or attachment is so attached, a default operating program or algorithm may be read or selected by, or transmitted to, controller 122 to thereby control the operation of the display device 16 as well as the other aspects and functions of the electro-mechanical surgical device 10. If the circular surgical stapler attachment 250 illustrated in Figure 9a is attached to flexible shaft 20, display device 16 may display, for example, data indicative of the gap between the anvil 256 and the body portion 10 252 as determined in accordance with the output signal of encoders 106, 108, as more fully described hereinabove.

Similarly, the indicators 18a, 18b are operated and controlled by controller 122 in accordance with the operating program or algorithm corresponding to the surgical instrument or attachment, if any, attached to the flexible shaft 20. Indicator 18a and/or indicator 18b may include an audio output device, such as a speaker, a buzzer, etc., and/or a visual indicator device, such as an LED, a lamp, a light, etc. If the circular surgical stapler attachment 250 illustrated in Figure 9a is attached to the flexible shaft 20, indicator 18a may indicate, for example, that the electro-mechanical surgical device 10 is in a power ON state, and indicator 18b may, for 15 example, indicate whether the gap between the anvil 256 and the body portion 252 is determined to be within the acceptable range as more fully described hereinabove. It should be appreciated that although only two indicators 18a, 18b are described, any number of additional indicators may be provided as necessary. Additionally, it should be appreciated that although a single display device 16 is 20 described, any number of additional display devices may be provided as necessary.

5

The display device 16' and indicators 18a', 18b' of wireless RCU 150 and the display device 16" and indicators 18a", 18b" of wired RCU 148 are similarly operated and controlled by respective controller 322, 322' in accordance with the operating program or algorithm corresponding to the surgical instrument or attachment, if any, attached to the flexible shaft 20.

Referring now to Figure 13, there is seen a flowchart of a first example embodiment of a main operating program according to the present invention. The main operating program begins at step 1000 and proceeds to step 1002, during which the electro-mechanical surgical device 10 is initialized. Step 1002 may include initialization steps, such as memory population and initialization, diagnostic self-testing, etc. After initialization step 1002, it is determined in step 1004 whether a surgical instrument or attachment ("DLU") is present -- that is, installed on the distal end 24 of flexible shaft 20. If it is determined in step 1004 that no DLU is present, control is transferred to loop 1034. If it is determined that a DLU is present, the operating program proceeds to step 1006, in which it is determined whether the FIRE key is pressed. FIRE key, in this context, refers to one of the switches of the wireless RCU 148 and/or wired RCU 150. More particularly, the FIRE key may correspond to switch 320 of wireless RCU 148 and/or switch 320' of wired RCU 150. If it is determined in step 1006 that FIRE key is pressed, control is transferred 20 to routine A in step 1008. Routine A is specific to the DLU, if any, attached to the flexible shaft 20. Routine A is more fully described hereinbelow and in Figures 14a to 14d. After the execution of routine A in step 1008, control is transferred to loop 1034.

25

If it is determined in step 1006 that the FIRE key is not pressed, it is determined in step 1010 whether the CLAMP key is pressed. In this context, the

TOP SECRET//NOFORN

CLAMP key refers to one of the switches of the wireless RCU 148 and/or wired RCU 150. More particularly, CLAMP switch may correspond to, for example, switch 316 of wireless RCU 148 and/or to switch 316' of wired RCU 150. If it is determined in step 1010 that CLAMP key is pressed, control is transferred to routine B in step 5 1012. Routine B is specific to the DLU, if any, attached to the flexible shaft 20.

Routine B is more fully described hereinbelow and in Figures 15a and 15b. After the execution of routine B in step 1012, control is transferred to loop 1034.

If it is determined in step 1010 that the CLAMP key is not pressed, it is determined in step 1014 whether the UNCLAMP key is pressed. In this context, the 10 UNCLAMP key refers to one of the switches of the wireless RCU 148 and/or wired RCU 150. More particularly, the UNCLAMP switch may correspond to, for example, switch 318 of wireless RCU 148 and/or to switch 318' of wired RCU 150. If it is determined in step 1014 that UNCLAMP key is pressed, control is transferred to routine C in step 1016. Routine C is specific to the DLU, if any, attached to the 15 flexible shaft 20. Routine C is more fully described hereinbelow and in Figure 16.

After the execution of routine C in step 1016, control is transferred to loop 1034.

If it is determined in step 1014 that the UNCLAMP key is not pressed, it is determined in step 1018 whether one or more of STEERING keys are pressed. In this context, the STEERING keys refer to respective switches of the wireless RCU 20 148 and/or wired RCU 150. More particularly, the STEERING keys may correspond to switches 302, 304, 306, 308 of wireless RCU 148 and/or switches 302', 304', 306', 308' of wired RCU 150. If it is determined in step 1018 that one or more STEERING keys are pressed, operation of respective steering motor(s) is performed in step 1020. The steering motors may correspond to third motor 84 and fourth

motor 92 as more fully set forth above. After the execution of step 1020, control is transferred to loop 1034.

If it is determined in step 1018 that none of the STEERING keys is pressed, it is determined in step 1022 whether the DISENGAGE key is pressed. In this context, 5 the DISENGAGE key refers to one of the switches of wireless RCU 148 and/or wired RCU 150. More particularly, DISENGAGE key may correspond to switch 312 of wireless RCU 148 and/or switch 312' of wired RCU 150. If it is determined in step 1022 that the DISENGAGE key is pressed, a disengage operation is performed in step 1024. After the execution of step 1024, control is transferred to loop 1034.

10 If it is determined in step 1022 that DISENGAGE key is not pressed, an IDLE routine is performed in step 1026.

In step 1028, it is determined whether to end the operation of the main operating program. If it is determined in step 1028 to not end the operation of the main operating program, control is transferred to loop 1034. If, however, it is determined in step 1028 to end or terminate the operation of the main operating 15 program, a shutdown routine is executed in step 1030, and the main operating program is thereafter terminated in step 1032.

It should be appreciated that the main operating program may determine which, if any, key is pressed in the order illustrated in Figure 13 or in any other 20 appropriate order. It should also be appreciated that the main operating program illustrated in Figure 13, as well as the routines illustrated in Figures 14a to 14d, 15a, 15b and 16, may be embodied, for example, in a messaging-based, event-driven and/or polling-type software application.

Referring now to Figures 14a to 14d, there is seen a flowchart of a first 25 example embodiment of a fire routine specific to a circular surgical stapler

attachment 250, such as that illustrated in Figure 9a, or 2250, such as that illustrated in Figures 9b and 9c. It should be appreciated that the fire routine illustrated in Figures 14a to 14d represents the routine A of step 1008 of the main operating program illustrated in Figure 13 and that the firing routine illustrated in Figures 14a to 14d is specific to a circular surgical stapler attachment 250, such as that illustrated in Figure 9a, or 2250, such as that illustrated in Figures 9b and 9c. It should be further appreciated that other surgical instruments or attachments, such as those enumerated above, may have other firing routines associated therewith.

Proceeding from step 1008, it is determined in step 1100 whether the DLU --  
10 the circular surgical stapler attachment 250 -- has been fully opened. This determination may be made based on the signals generated by the encoders 106, 108, as more fully described above. If it is determined in step 1100 that the DLU has not been fully opened, an ERROR condition is determined in step 1102 in that the DLU is not ready for firing. Control is then transferred to step 1120, wherein  
15 control returns to the main operating program illustrated in Figure 13.

If it is determined in step 1100 that the DLU has been fully opened, it is determined in step 1104 whether the DLU has been fully clamped. This determination may be made based on the signals generated by the encoders 106, 108, as more fully described above. If it is determined in step 1104 that the DLU  
20 has not been fully clamped, an ERROR condition is determined in step 1106 in that the DLU is not within an acceptable range for firing. Control is then transferred to step 1120, wherein control returns to the main operating program illustrated in Figure 13.

If it is determined in step 1104 that the DLU has been fully clamped, it is determined in step 1108 whether the DLU has been previously fired. This

determination may be made based on the signals generated by the encoders 106, 108 and/or in accordance with usage data 184. If it is determined in step 1108 that the DLU has been previously fired, an ERROR condition is determined in step 1110 in that the DLU has been used. Control is then transferred to step 1120, wherein

5 control returns to the main operating program illustrated in Figure 13. It should be appreciated that a similar usage determination may be made in the main operating program illustrated in Figure 13, for example, in the initialization step 1002 or in the DLU presence determining step 1004, as an alternative or in addition to the determining step 1108.

10 If it is determined in step 1108 that the DLU has not been previously fired, a usage count is decremented in step 1112. The usage count may be stored in usage data 184 as more fully described hereinabove. Several attempts at decrementing the usage count may be made in step 1112. However, a failure to decrement the usage count may nevertheless occur. In step 1114, it is determined whether the usage count decrementing step 1112 has failed. If it is determined in step 1114 that the decrementing of usage count failed, a ERROR condition is determined in step 1116. Thereafter, in step 1118, a wait loop is executed until all keys of the wireless RCU 148 and/or wired RCU 150 have been released. After it is determined in step 15 1118 that all keys have been released, control is transferred to step 1120.

20 Thereafter, control returns to the main operating program illustrated in Figure 13.

If it is determined in step 1114 that the usage count decrementing did not fail, the firing motor current limit is set in step 1122. In this context, the firing motor may correspond to the second motor 80 as more fully described hereinabove. The firing motor is then started in step 1124 to begin the advancement of the staple

25 driver/cutter 264.

Referring now to Figure 14b, a timer is set in step 1126. It is thereafter determined in step 1128 whether the time elapsed for the firing operation has exceeded a predetermined threshold. If it is determined in step 1128 that the firing time limit has been exceeded, the firing motor is disabled in step 1130, and an

5      ERROR condition is determined in step 1132. Control then proceeds to step 1136.

If, however, it is determined in step 1128 that the firing time has not exceeded the predetermined firing time limit, it is determined in step 1134 whether a hardware current limit has been exceeded. The hardware current limit relates to the resistance of the firing motor to continued operation. A condition that the hardware current limit has been exceeded is indicative that the stapling operation has been successfully completed. If it is determined in step 1134 that the hardware current limit has not been exceeded, the operation of firing motor is continued until either the predetermined firing time limit has been exceeded or the hardware current limit has been exceeded. In either instance control proceeds thereafter to step 1136.

15      Step 1136 represents a waiting step, during which a predetermined wait time is permitted to elapse. This wait time permits the driving and driven elements of electro-mechanical surgical device 10 and circular surgical stapler attachment 250 to come to rest before proceeding to step 1138, in which step the firing motor is stopped.

20      After the firing motor is stopped in step 1138, the motor current limit is set to full scale in step 1140, and then the firing motor is started in step 1142 in a reverse direction to retract the staple driver/cutter 264 and return the same to its initial position. Then, once the gap between the anvil 256 and the body portion 252 has exceeded the acceptable range, the indicator 18a, 18b corresponding to an

25      IN-RANGE indicator is turned off in step 1144. Alternatively, the IN-RANGE

indicator may be turned off in step 1144 upon the start of the reversal of the motor in step 1142. After the IN-RANGE indicator is turned off in step 1144, the timer is reset in step 1146.

Referring now to Figure 14c, it is determined in step 1148 whether a

5 predetermined time limit for completing the retraction of the staple driver/cutter 264, based on the timer reset in step 1146, has been exceeded. If it is determined in step 1148 that the predetermined time limit has been exceeded, an ERROR condition is determined in step 1150 in that the retraction operation failed to be completed within the permissible predetermined time limit. If, however, it is  
10 determined in step 1148 that the predetermined time limit has not been exceeded, it is determined in step 1152 whether retraction of the staple driver/cutter 264 has been completed. If it is determined in step 1152 that the retraction of the staple driver/cutter 264 has not been completed, control returns to step 1148. Retraction of staple driver/cutter 264 continues until either the predetermined time limit has been exceeded as determined in step 1148 or the retraction has been completed as  
15 determined in step 1152. It should be appreciated that the determination made in step 1152 may be based on the signals generated by the encoders 106, 108. After it is determined that the retraction of staple driver/cutter 264 has been completed (step 1152) or that the predetermined time limit has been exceeded (step 1148), the  
20 unclamp motor current limit is set of full scale in step 1154. In this context, the unclamp motor may correspond to first motor 76 as more fully described hereinabove.

In step 1156, the halfway point between the current position of the anvil 256 and the final, unclamped position of the anvil 256 is calculated. A "phantom" destination position is set in step 1158 to a predetermined setpoint plus a

predetermined bias value to ensure that the unclamp motor achieves its maximum, or full, current to thereby ensure the maximum torque output from the unclamp motor. In step 1160, the movement of the unclamp motor is initiated. In step 1162, the timer is set, and in step 1164 a destination flag is cleared.

5 Referring now to Figure 14d, it is determined in step 1166 whether the anvil 256 has passed the halfway point determined in step 1156. If it is determined in step 1166 that the anvil 256 has passed the halfway point determined in step 1156, the "true" final destination position for the anvil 256 is set in step 1170, thereby superceding the "phantom" final destination set in step 1158. Control is then  
10 transferred to step 1174. If, however, it is determined in step 1166 that the position of the anvil 256 is not past the halfway point determined in step 1156, control is directly transferred to step 1174, bypassing the destination resetting step 1170.

In step 1174, it is determined whether the anvil 256 has reached the "true" final destination set in step 1170. It should be appreciated that the position of the anvil 256 may be determined in accordance with the signals output by encoders 106, 108 as more fully described hereinabove. If it is determined in step 1174 that anvil 256 has reached its "true" final destination set in step 1170, control is transferred to step 1180, described below. If, however, it is determined in step 1174 that the "true" final destination of the anvil 256 has not been reached, it is  
15 determined in step 1176, with reference to the timer reset in step 1162, whether a predetermined time limit has been exceeded. If it is determined in step 1176 that the predetermined time limit has not been exceeded, control is returned to step 1166, and the unclamp motor continues its operation to further unclamp the anvil 256. If, however, it is determined in step 1176 that the predetermined time limit has  
20 been exceeded, and ERROR condition is determined in step 1178 in that the anvil  
25

PCT/US2006/032250

256 could be moved into its "true" final destination within the predetermined time limit. Control is thereafter transferred to step 1180, in which the steering mechanism is disengaged. In the example embodiment of electro-mechanical surgical device 10 described above, the steering mechanism may include the fifth motor 96 and/or carriage 100 as more fully described hereinabove. After the steering mechanism has been disengaged in step 1180, a wait loop is executed in step 1182 until all keys of wireless RCU 148 and/or wired RCU 150 have been released. Once all of the keys have been released, control returns in step 1184 to the main operating program illustrated in Figure 13.

Referring now to Figures 15a and 15b, there is seen a flowchart of a first example embodiment of a clamp routine specific to a circular surgical stapler attachment 250, such as that illustrated in Figure 9a, or 2250, such as that illustrated in Figures 9b and 9c. It should be appreciated that the clamp routine illustrated in Figures 15a and 15b represents the routine B of step 1012 of the main operating program illustrated in Figure 13 and that the clamp routine illustrated in Figures 15a and 15b is specific to a circular surgical stapler attachment 250, such as that illustrated in Figure 9a, or 2250, such as that illustrated in Figures 9b and 9c. It should be further appreciated that other surgical instruments or attachments, such as those enumerated above, may have other clamping routines associated therewith.

Proceeding from step 1012, it is determined in step 1200 whether a DLU open flag is set. If it is determined in step 1200 that the DLU open flag is not set, an ERROR condition is determined in step 1202 in that the DLU is not ready to clamp. A wait loop is executed thereafter in step 1204, and once all keys of wireless RCU

148 and/or wired RCU 150 have been released, control returns in step 1206 to the main operating program illustrated in Figure 13.

If, however, it is determined in step 1200 that the DLU open flag is set, it is determined in step 1208 whether the gap between the anvil 256 and the body portion 252 is greater than a predetermined threshold  $G_1$ , such as, for example, 5.0 mm. This determination may be made based on the signals generated by the encoders 106, 108, as more fully described above. If it determined that the gap between the anvil 256 and the body portion 252 is less than the predetermined threshold  $G_1$ , control proceeds to step 1220. If, however, it is determined in step 1208 that the gap between the anvil 256 and the body portion 252 is greater than the predetermined threshold  $G_1$ , control proceeds to step 1210 in which a CLAMP motor speed and torque limit are set to the respective maximum values. In this context, the CLAMP motor may correspond to first motor 76 as more fully described hereinabove. A timer is reset in step 1212, and the control loop of steps 1214 and 1218 is executed until either a predetermined time period for reaching a gap of less than the predetermined threshold  $G_1$  is exceeded or the gap is determined to be less than the predetermined threshold  $G_1$ . If it is determined in step 1214 that the predetermined time period has been exceeded, an ERROR condition is determined in step 1216 in that the clamp operation is considered to have failed. After step 20 1216 is performed, step 1204 is performed, in which a wait loop is executed until all keys of wireless RCU 148 and/or wired RCU 150 have been released. Thereafter, control returns in step 1206 to the main operating program illustrated in Figure 13.

If it is determined in step 1214 that the predetermined time period has not been exceeded, it is determined in step 1218 whether the movement of the anvil 256 to a location in which the gap between the anvil 256 and the body portion 252 is less

than the predetermined threshold  $G_1$  has been completed. If it is determined in step 1218 that this move has not been completed, the operation of CLAMP motor is continued, and control returns to step 1214. If however, it is determined in step 1218 that the move is complete, control proceeds to step 1220.

5 In step 1220, a speed lower than the maximum speed set in step 1210 is set for the CLAMP motor and a torque limit lower than the torque limit set in step 1210 is set for the CLAMP motor. Thereafter, in step 1222, a position bias is set to ensure that the CLAMP motor outputs full torque when the gap between the anvil 256 and the body portion 252 approaches the bias value. The bias value may be, for  
10 example, approximately 1.0 mm to ensure full torque output from the CLAMP motor when the gap is approximately equal to 1.0 mm.

Referring now to Figure 15b, control proceeds to step 1224, in which a timer is reset. In step 1226, the value of the current gap between the anvil 256 and the body portion 252 is displayed on the display device 16. In step 1228, it is determined whether the gap between the anvil 256 and the body portion 252 is less than a predetermined threshold  $G_2$ . This determination may be made based on the signals generated by the encoders 106, 108, as more fully described above. The predetermined threshold  $G_2$  may be, for example, 2.0 mm. If the gap between the anvil 256 and the body portion 252 is determined in step 1228 to be less than the  
15 predetermined threshold  $G_2$ , control proceeds to step 1230, in which an IN-RANGE indicator is activated and a DLU ready flag is set. The IN-RANGE indicator may correspond to one of the indicators 18a, 18b, either one or both of which may be, for example, LED elements or other audio or visual indicators. If it is determined in step 20 1228 that the gap between the anvil 256 and the body portion 252 is not less than the predetermined threshold  $G_2$ , control proceeds to step 1232, in which it is

determined whether the gap between the anvil 256 and the body portion is less than or equal to another predetermined threshold  $G_3$ . This determination may be made based on the signals generated by the encoders 106, 108, as more fully described above. The predetermined threshold  $G_3$  may be, for example, 1.0 mm. If it is determined in step 1232 that the gap between the anvil 256 and the body portion 252 is less than or equal to the predetermined threshold  $G_3$ , control proceeds to step 1238, described below. However, if it is determined in step 1232 that the gap between the anvil 256 and the body portion 252 is greater than the predetermined threshold  $G_3$ , it is determined in step 1234 whether the current limit to the CLAMP motor has been reached for a predetermined time limit. That the current limit to the CLAMP motor has been reached for the predetermined time limit is indicative that tissue is fully clamped between the anvil 256 and the body portion 252. The predetermined time limit may be, for example, 1.0 second. If it is determined in step 1234 that the current limit to the CLAMP motor has been reached for the predetermined time limit, control proceeds to step 1238. If, however, it is determined in step 1234 that the current limit to the CLAMP motor has not been exceeded for the predetermined time limit, it is determined in step 1236 whether the CLAMP key has been released. If it is determined in step 1236 that the CLAMP key has not been released, control returns to step 1226. If it is determined in step 1236 that the CLAMP key has been released, control proceeds to step 1238.

In step 1238, the operation of the CLAMP motor is stopped. Thereafter, in step 1240, a wait loop is executed until all keys of wireless RCU 148 and/or wired RCU 150 have been released. After all keys have been released, control returns in step 1242 to the main operating program illustrated in Figure 13.

0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

Referring now to Figure 16, there is seen a flowchart of a first example embodiment of an unclamp routine specific to a circular surgical stapler attachment 250, such as that illustrated in Figure 9a, or 2250, such as that illustrated in Figures 9b and 9c. It should be appreciated that the unclamp routine illustrated in Figure 16 represents the routine C of step 1016 of the main operating program illustrated in Figure 13 and that the unclamp routine illustrated in Figure 16 is specific to a circular surgical stapler attachment 250, such as that illustrated in Figure 9a, or 2250, such as that illustrated in Figures 9b and 9c. It should be further appreciated that other surgical instruments or attachments, such as those enumerated above, may have other unclamp routines associated therewith.

Proceeding from step 1016, a torque limit for an UNCLAMP motor is set in step 1300 to its maximum value. The UNCLAMP motor may correspond to the CLAMP motor as more fully described hereinabove. The UNCLAMP motor may also correspond to the first motor 76 as more fully described hereinabove.

In step 1302, the destination position for the anvil 256 is set to a value representative of its fully unclamped position. The operation of the UNCLAMP motor is initiated in step 1304. In step 1306, it is determined whether the UNCLAMP key has been released. If it is determined in step 1306 that the UNCLAMP key has been released, control proceeds to step 1314. If it is determined in step 1306 that the UNCLAMP key has not been released, it is determined in step 1308 whether the gap between the anvil 256 and the body portion 252 is greater than or equal to a predetermined threshold  $G_4$ , which is defined in accordance with the destination position set in step 1302. This determination may be made based on the signals generated by the encoders 106, 108, as more fully described above. If it is determined in step 1308 that the gap between the anvil 256 and the body portion

252 is greater than or equal to the predetermined threshold  $G_4$ , a DLU opened flag is set in step 1310. Control then proceeds to step 1312. If it is determined in step 1308 that the gap between the anvil 256 and the body portion 252 is less than the predetermined threshold  $G_4$ , it is determined in step 1312 whether the unclamp operation is complete. That is, whether the destination position for the anvil 256 set in step 1302 has been reached. If it is determined in step 1312 that the movement of the anvil 256 is not complete, control returns to step 1306. If it is determined in step 1312 that the movement of the anvil 256 is complete, the operation of the UNCLAMP motor is stopped in step 1314. Control then returns in step 1316 to the main operating program illustrated in Figure 13.

Figures 17a to 17d illustrate a flowchart of a second example embodiment of a main operating program for operating the electro-mechanical surgical device illustrated in Figure 1. Figures 18a and 18b illustrate a flowchart of a self-test operating program for the electro-mechanical surgical device illustrated in Figure 1. Figures 19a to 19e illustrate a flowchart for a field test operating program for the electro-mechanical surgical device illustrated in Figure 1. Figures 20a to 20c illustrate a flowchart for a main operating program for operating the circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c. Figures 21a to 21d illustrate a flowchart of a second example embodiment of a fire routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c. Figures 22a and 22b illustrate a flowchart of a second example embodiment of a clamp routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c. Figures 23a and 23b illustrate a flowchart of a second example embodiment of an unclamp routine for a circular surgical stapler attachment, such as that illustrated in Figures 9a to 9c. The operating programs illustrated in Figures 17a to 23b are

readily understood by those skilled in the art, and a further description thereof is not included herein.

It should be understood that the operation of the several motors and switch elements as described above with respect to the circular surgical stapler attachment

5 250, 2250 are specific to the circular surgical stapler attachment 250, 2250. The motor(s) and/or switch(es) may perform other functions when other surgical instruments or attachments are attached to flexible shaft 20.

It should be appreciated that the surgical instrument or attachment, such as,

for example, the circular surgical stapler attachment 250 illustrated in Figure 9a or

10 the circular surgical stapler attachment 2250 illustrated in Figure 9b, may be configured to be attached to the flexible shaft 20 either extracorporeally or intracorporeally. Intracorporeal attachment of the surgical instrument or attachment may result in, for example, reduced trauma and improved recovery time. For example, conventional linear cutter devices and linear stapler devices have been used to perform functional end-to-end anastomosis procedures along the intestinal tract. Due to the length, small diameter, flexibility and steerability of the flexible shaft

20, the flexible shaft 20, without any surgical instrument or attachment attached thereto, may be entered into the body, such as, for example, into to gastrointestinal

15 tract via the mouth or the rectum with minimal trauma. It should be appreciated that

20 the flexible shaft 20 may be entered into the body via, for example, a natural orifice, an incision, a cannula, etc. The flexible shaft 20 may then be further inserted into the body and steered, as more fully set forth above, so that the distal end 24 of the flexible shaft 20 is delivered to the treatment site, such as, for example, along the intestinal tract. Then, after the distal end 24 of the flexible shaft 20 has been

25 delivered to the treatment side, the surgical instrument or attachment is attached to

the flexible shaft 20 via the second coupling 26 in situ. The surgical instrument or attachment may be inserted into the body for attachment to the flexible shaft 20 via a natural orifice, an incision, a cannula, etc. It should be appreciated that the flexible shaft 20 may be entered into the body via a first orifice and that the surgical

5 instrument or attachment may be entered into the body via a second orifice, the first orifice being the same as or different than the second orifice.

With the surgical instrument or attachment so attached to the flexible shaft 20, an end-to-end anastomosis procedure, for example, may be performed and the flexible shaft 20 with the surgical instrument or attachment attached thereto may thereafter be withdrawn from the body. It should be appreciated that the surgical instrument or attachment may be shaped and configured to minimize trauma during withdrawal thereof. Furthermore, it should be appreciated that the flexible shaft 20 may be caused to become limp prior to withdrawal from the body as more fully described above.

Thus, the several aforementioned objects and advantages of the present invention are most effectively attained. Those skilled in the art will appreciate that numerous modifications of the exemplary embodiment described hereinabove may be made without departing from the spirit and scope of the invention. Although a single exemplary embodiment of the present invention has been described and disclosed in detail herein, it should be understood that this invention is in no sense limited thereby and that its scope is to be determined by that of the appended claims.